UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,908	01/15/2004	Bryan W. Wolf	6925.US.C1	4794

25755 7590 06/26/2006

ROSS PRODUCTS DIVISION OF ABBOTT LABORATORIES
DEPARTMENT 108140-DS/1
625 CLEVELAND AVENUE
COLUMBUS, OH 43215-1724

EXAMINER	
MAIER, LEIGH C	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 06/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/757,908	WOLF, BRYAN W.	
	Examiner	Art Unit	
	Leigh C. Maier	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/15/04;3/21/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3 and 10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that Applicant, at the time the application was filed, had possession of the claimed invention.

The claims recite a method wherein pullulan is "administered as a single entity selected from the group consisting of powder, pills, [etc.]." The examiner does not find support for the method wherein the pullulan is administered simply as a powder.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6 and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Hiji (US 4,913,925).

Hiji discloses the administration of a beverage comprising 5g of pullulan to human subjects. See example 4. The methods are anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 4-6, 8, 9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hiji (US 4,913,925).

Hiji teaches as set forth above. The reference further teaches that the administration of pullulan results in the inhibition of postprandial blood glucose increase. See col 1, lines 48-58 and examples. Example 5 exemplifies the treatment of prediabetes-prone patients. The reference teaches the control of hyperglycemia but does not explicitly suggest the treatment of diabetics, per se. The reference further teaches a dosage of pullulan wherein the ratio of pullulan to sucrose and/or starch in the diet is in the range of 1:400 to 1:20. See col 2, lines 47-54.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to administer pullulan to diabetics in order to manage blood glucose levels/produce a blunted glycemic response because Hiji had taught that administration of pullulan inhibits postprandial blood glucose increase. Although the reference does not teach the treatment of diabetics, per se, a practitioner of ordinary skill would be aware that a diabetic, in particular, is one in need of this treatment. In the absence of unexpected results, the practitioner

would reasonably expect success in implementing such treatment. It would be within the scope of the artisan to optimize the dosage through routine experimentation. In implementing the treatment as taught in the reference, providing for the prolonged release of glucose, assisting in weight loss and prevention of hypoglycemia would also be accomplished.

Claims 3 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hiji (US 4,913,925) as applied to claims 1, 2, 4-6, 8, 9 and 11 above, and further in view of Nakamura et al (US 4,623,394).

Hiji teaches as set forth above. The reference does not teach the administration in the form of capsules, tablets, etc.

Nakamura teaches the preparation of pullulan in the form of capsules, tablets, etc.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to administer pullulan in the form of a capsule, tablet, etc. to control hyperglycemia in a diabetic. Nakamura had taught that pullulan may be prepared in these dosage forms. In the absence on unexpected results, the artisan would be motivated to administer pullulan in such a form for situations where pullulan-containing foodstuff is not available conveniently, such as when the patient is dining in a restaurant. The examiner finds no evidence of criticality in the administration of any "non-food" form of pullulan. In administering the pullulan in this form for blunting the glycemic response in the diabetic patient, promotion of weight loss would also be accomplished.

Claims 1, 2, 4-9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kato (US 3,875,308).

Kato teaches the replacement of starch by pullulan in food products for diabetics and those in need of weight loss. See col 2, lines 26-46. The reference is silent regarding the effect on blood glucose levels.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to replace some or all of the starch with pullulan in food for diabetics and those in need of weight loss in the amounts set forth in the reference. For example, example 2 describes a recipe for cookies comprising 100 g of pullulan. It would appear that this recipe would result in far fewer than 100 average sized cookies. Therefore, administering a single cookie to one in need would accomplish the methods. In administering the food products in the reference to the described patient populations, all of the methods would be accomplished even if some of them, such as effect on blood glucose levels, were not recognized at the time.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claims because the examined application claim is either anticipated by, or would have been obvious over, the reference claims.

See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 2 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 6,916,796. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The method of '796 recites the administration of pullulan in the form of a meal replacement but does not recite a particular amount of pullulan. However, in preparing a meal replacement, one of ordinary skill would prepare a product having enough calories in a meal, say about 500 calories for a conservative 1500 calorie diet. A product wherein at least 25% of the calories are in the form of carbohydrate and at least 5% of the carbohydrate is in the form of pullulan, would comprise 125 g carbohydrate ÷ 4 calories/g of carbohydrate, or 31.25 g of

carbohydrate, with 5% of that weight, or 1.6 g, being pullulan. At 80% carbohydrate, the product would comprise 5 g of pullulan. Therefore, in carrying out the method of '796 as described, the instant method would be accomplished.

Claims 4-9 and 11 are also rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 10 of U.S. Patent No. 6,916,796. In administering a meal replacement, as described above, in order to provide nutrition to a diabetic patient, the instant methods of claims 4-9 and 11 would also be accomplished.

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Thursday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Anna Jiang (571) 272-0627, may be contacted. The fax number for Group 1600, Art Unit 1623 is (571) 273-8300.

Visit the U.S. PTO's site on the World Wide Web at http://**www.uspto.gov**. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more. Information regarding the status of an application may be obtained from the Patent Application Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished application is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

Leigh C. Maier

Leigh C. Maier
Primary Examiner
June 19, 2006